PBD-02421
0096 email.pdf
HMR3647 (Ketek)
Aventis - Confidential

Subject: RE: Protocol Violation Tracker
Date: Wed, 19 Jun 2002 11:55:19 -0500
From: <Nadine.Grethe@aventis.com>
To: jean.noone@rtp.ppdi.com
CC: cathy.tropmann@rtp.ppdi.com, teresa.dunlap@rtp.ppdi.com, master.treat@rtp.ppdi.com

At this point it is too late to change anything in the database. They filled it out with an informed consent dae and that is what we are going with. We arenot changing this again. They screwed up, they will now have to take the blame. Also If they keep changing their minds then I really do not believe them now.

-----Original Message-----
From: Jean Noone [mailto:jean.noone@rtp.ppdi.com]
Sent: Wednesday, June 19, 2002 11:30 AM
To: Grethe, Nadine I. PH/US
Cc: Cathy Tropmann; Teresa Dunlap; Jean Noone; Master TREAT
Subject: Protocol Violation Tracker

Nadine, attached is the PVT.

Unfortunately, we are still getting conflicting information from sites. They will tell us one thing, then the next time we call, they tell us the opposite. This is particularly problematic when it comes to whether a subject was ever consented or not, and what study drug the subject took.

ICF Issues
Since the database lock, we have learned of 4 additional subjects who NEVER signed an ICF and 1 subject who the site now insists DID sign the ICF, even though they previously told us the subject didn't. That means data for the 4 are in the database (and should not be) and data for the 1 subject isn't in the database and should be. The new subjects who are now classified as Never Consented are:
0095-023 (this is the only one that drug was dispensed to.....but she didn't take any)
403-020
506-043
2011-004
The 1 subject who previously was Never Consented but now should be in the database is:
1238-003

Treatment Arm issues
For the following subjects, the sites are now saying the treatment on the CRF is incorrect:
24-001 really received Ketek, as per randomization, not Augmentin as on the CRF and signed query reply
96-004 and 96-084 really received Ketek, as per randomization, not Augmentin as on the CRF
405-022 subject really received Ketek, even though randomized to Augmentin and signed query reply states Augmentin given.
1447-009 really received Augmentin as per randomization even though signed query reply and label on CRF says Ketek.
2125-001 Subject was first randomized as "572" (site entered initials on phone pad rather than subject number) to Ketek and received Ketek. Then site re-randomized that patient, the second time using "001" and the patient was randomized to Augmentin. Data under "572" was dummied out of IVR, rather than dummying out "001's" data and changing 572 to 001. That means the random table is wrong for this subject....it should be Ketek rather than